

(4) The interior of the hood, glove box, or cabinet containing the chamber and all items will be decontaminated periodically, for example, at the end of a series of related experiments. Until decontaminated, the hood, box, or cabinet will be posted to indicate that toxins are in use, and access to the equipment and apparatus restricted to necessary, authorized personnel.

§ 627.18 Emergencies.

(a) *Introduction.* All laboratories will establish specific emergency plans for their facilities. Plans will include liaison through proper channels with local emergency groups and with community officials. These plans will include both the building and the individual laboratories. For the building, the plan must describe evacuation routes, facilities for medical treatment, and procedures for reporting accidents and emergencies. The plans will be reinforced by drills. Emergency groups and community officials must be informed of emergency plans in advance of any call for assistance. See AR 385-69.

(b) *General emergency procedures.* The following emergency procedures will be followed for laboratory accidents or incidents—

(1) Using appropriate personal protection, assist persons involved, remove contaminated clothing if necessary, decontaminate affected areas, and remove personnel from exposure to further injury if necessary; do not move an injured person not in danger of further harm. Render immediate first aid if necessary.

(2) Warn personnel in adjacent areas of any potential hazards to their safety.

(3) In case of fire or explosion, call the fire department or community fire brigade immediately. Follow local rules for dealing with incipient fire. Portable fire extinguishers will be made available with instructions for their use. Fire fighters responding to the fire scene will be advised to wear a self-contained positive pressure breathing apparatus to protect themselves from toxic combustion by-products.

(4) Laboratories must be prepared for problems resulting from severe weather or loss of a utility service. In the event of the latter, most ventilation systems

not supplied with emergency power will become inoperative. All potentially hazardous laboratory work must stop until service has been restored and appropriate action has been taken to prevent personnel exposure to etiologic agents.

(5) In a medical emergency, summon medical help immediately. Laboratories without a medical staff must have personnel trained in first aid available during working hours.

(6) For small-scale laboratory accidents, secure the laboratory, leave the area, and call for assistance.

(7) When handling mixed hazards (for example, a substance or mixture that may be infectious and radioactive, or infectious and chemically toxic), respond with procedures addressing the greater hazard first, and then follow through with those for the lesser hazards to ensure that all appropriate steps have been taken.

(c) *Evacuation procedures.* Building and laboratory evacuation procedures will be established and communicated to all personnel.

(1) Emergency alarm system. (i) There will be a system to alert personnel of an emergency that requires evacuation of the laboratory or building. Laboratory personnel must be familiar with the location and operation of alarm equipment.

(ii) Isolated areas (for example, cold, warm, or sterile rooms) will be equipped with an alarm or communication system that can be used to alert others outside to the presence of a worker inside, or to warn workers inside of an emergency that requires evacuation.

(2) Evacuation routes will be established and an outside assembly area for evacuated personnel must be designated. All individuals should be accounted for.

(3) Shut-down and start-up procedures.

(i) Guidelines for shutting down operations during an emergency evacuation will be available in writing. Those guidelines will include procedures for handling any power failure emergency.

(ii) Written procedures will also be provided to ensure that personnel do not return to the laboratory until the emergency is ended. Those procedures

must also contain start-up operations for the laboratory.

(iii) All shut-down and start-up procedures will be available to personnel and reviewed semiannually.

(4) All aspects of the building evacuation procedure will be tested semiannually with practice drills.

(d) *Spills.* (1) All areas where work with etiologic agents is performed will have designated personnel to respond to a spill and provide protective apparel, safety equipment, and materials necessary to contain and clean up the spill. Protective clothing requirements are described in §627.21. Also, there will be supplies on hand to deal with the spill consistent with the hazard and quantities of the spilled substance.

(2) The safety officer will be notified immediately of all spills. The first line supervisor will ensure that proper clean-up techniques are employed.

(3) Etiologic agents. (i) A program for responding to spills of etiologic agents will be developed and implemented. This program will contain emergency response procedures for a biological spill, which will be tailored to the potential hazard of the material being used, the associated laboratory reagents involved, the volume of material, and the location of the materials within the laboratory. Generally, the spill should be confined to a small area while minimizing the substance's conversion to an aerosol. The spill will be chemically decontaminated or neutralized, followed by a cleanup with careful disposal of the residue. If the spilled material is volatile and noninfectious, it may be allowed to evaporate but must be exhausted by a chemical hood or ventilation system.

(ii) When a mishap occurs that may generate an aerosol of etiologic agents requiring BL-2 (or higher) containment, the room must be evacuated immediately, the doors closed, and all clothing decontaminated, unless the spill occurs in a class II or class III biological safety cabinet. Sufficient time must be allowed for the droplets to settle and the aerosols to be reduced by the air changes of the ventilation system before decontaminating the area. The area will then be decontaminated to prevent exposure to the infectious agents or toxic substances. Reentry

procedures to perform the decontamination will conform to §627.18(e).

(iii) A spill of biohazardous material within a biological safety cabinet requires a special response and cleanup procedure. Cleanup will be initiated while the cabinet continues to operate, using an effective chemical decontaminating agent. Aerosol generation during decontamination and the escape of contaminants from the cabinet must be prevented. Caution must be exercised in choosing the decontaminant, keeping in mind that fumes from flammable organic solvents, such as alcohol, can reach dangerous concentrations within a biological safety cabinet.

(4) Combined radioactive and biological spills. (i) Both the radiation protection officer (RPO) and the safety officer must be notified immediately whenever there is a spill of radioactive biological material, regardless of its size. Laboratory personnel may be expected to clean up the spill. The RPO will direct the cleanup, in accordance with the NRC license for the facility.

(ii) The spill will be cleaned up in a way that minimizes the generation of aerosols and spread of contamination. All items used in cleaning up the spill must be disposed of as radioactive waste.

(iii) Following cleanup, the area, affected protective clothing, and all affected equipment and supplies must be surveyed for residual radioactive contamination. All potentially affected areas and items that are not disposable will be wipe-tested to verify that unfixed radioactive contamination has been removed. If fixed contamination is found, the RPO will determine the requirements for additional cleanup.

(e) *Reentry procedures.* This section applies when reentry is necessary to clean up a spill outside of a hood or biological safety cabinet, or to decontaminate or service engineering controls that have failed or malfunctioned so that they do not provide the required containment.

(1) When agents requiring BL-1 or BL-1 LS containment are involved, the clothing requirements stated in §627.30

(a) or (b) as appropriate will be followed. Individuals will remove the required protective clothing when finished and wash their hands before proceeding to other tasks.

(2) When agents requiring BL-2, BL-2 LS, or toxin procedures and containment are involved, personnel will be required to wear the clothing described in §627.30 (c) or (d) as appropriate. Outer protective clothing will be removed and left in the room before exiting and personnel will wash their hands before proceeding on to other activities.

(3) When agents requiring BL-3, or BL-3 LS containment are involved, containers for sealing up inner protective clothing and decontaminant will be placed at the room exit. Personnel will be required to wear the clothing described in paragraph 4-10e. When exiting the area after decontamination procedures, individuals will remove their outer layer of protective clothing just before exiting the room. Once outside the room, the inner layer of protective clothing (for example, coverall) will be removed and placed in the container and the inner gloves will be decontaminated before being removed and placed in the container. Personnel will proceed directly to the shower facility to take a complete shower before exiting the facility.

(4) When agents requiring BL-4 containment are involved, the following applies as appropriate to the type of BL-4 facility:

(i) When a spill requiring clean-up is in an area designed for use with personal positive pressure suits, the entry and exit procedures will be those normally required to enter or exit the area.

(ii) When entering a nonsuit area where a spill of etiologic agent has occurred outside the containment of a Class III biological safety cabinet, personnel will wear the clothing as described in §627.30(f). Before entry, decontamination areas will be established. To accomplish this, two step-in decontamination pans with the appropriate disinfectant will be set up [one just inside the room (where the contamination exists) and the second immediately outside the room]. Immediately outside the room, there will

also be a sealable container suitable for sealing up the suit and any air lines (if used).

(iii) When exiting the room, suited individuals will place all equipment and other items in autoclaves or disinfectant, step into the disinfectant pan, and wash down the exterior of their suits with appropriate disinfectant. When completed, the door to the room will be opened and the individual will step through the doorway into the second disinfectant pan. The suit will be thoroughly rinsed with disinfectant again before moving toward the exit from the facility. The suit (but not the respirator) will be placed in the provided container. The individual will proceed through another doorway before removing the respirator and placing it in a closed container for decontamination. The individual will then proceed directly to the shower area and take a full shower before exiting the area. In case they are needed, personnel will be standing by ready to render assistance. Suited individuals will be visually observed, if possible. When visual observation is not possible, a communications system is required.

(f) *Mishap reports and investigations.*
(1) Each institution must have a defined system for reporting laboratory injuries, illnesses, and mishaps, as well as for investigating them. These events will be documented and reported to the appropriate safety, supervisory, and occupational health personnel. Those organizations subject to the regulations promulgated by the OSHA will follow the specific requirements for reporting injuries in the work place contained in those regulations. The requirements stated in AR 385-69, State, and local government requirements for similar reporting will be followed.

(2) Form(s) for recording mishaps will be available and completed for all laboratory mishaps. Those reports must include a description of the mishap and any factors contributing to it. In addition, a description of any first aid or other health care given to the employee will be included. Responsibility for completing these forms must be clearly defined in the facility safety

manual. Mishaps will be reviewed periodically by the safety officer, the safety committee, the employee health unit, or other appropriate personnel. Individual reports or a summary must be sent, along with recommended changes in laboratory procedure or policy, to the commander or institute director. Policy or procedural changes must be implemented if deemed necessary by the commander or institute director.

(3) Any mishaps with etiologic agents used under sponsorship of the BDP that result in sero-conversion or a laboratory-acquired illness will be reported.

§ 627.19 Large-scale operations.

(a) *Large-scale.* In addition to the requirements stated in § 627.13, the following applies to research or production activities involving viable etiologic agents in quantities greater than 10 liters:

(1) All large-scale operations will be conducted in facilities described in § 627.47.

(2) Cultures will be handled in a closed system.

(3) Sample collection, the addition of materials, and the transfer of culture fluids shall be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces.

(4) A closed system or other primary containment equipment that has contained viable organisms shall not be opened for maintenance or other purposes unless it has been sterilized.

(5) SOPs will include a section describing and requiring a validation of the process equipment's proper function.

(6) Scientists, technicians, equipment workers, and support personnel with access to the large-scale production area during its operation will be included in the medical surveillance program.

(b) *BL-2—LS.* In addition to the requirements stated in §§ 627.19(a) and 627.14, the following procedures will be employed for BL-2—LS:

(1) Rotating seals and other mechanical devices directly associated with the closed system used for the propagation and growth of viable organisms shall be designed to prevent leakage or shall be fully enclosed in ventilated

housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through other equivalent treatment devices.

(2) A closed system used for the propagation and growth of viable organisms and other primary containment equipment used to contain operations involving viable organisms shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(3) Systems used to propagate and grow viable organisms shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment.

(c) *BL-3—LS.* In addition to the requirements stated in §§ 627.19(a) and 617.14, the following procedures apply:

(1) Personnel entry into the controlled area shall be through the entry area specified in § 627.47(c)(1).

(2) Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jumpsuits, long sleeved laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area, the work clothing may be stored in a locker separate from that used for personal clothing, or discarded for laundering. Clothing shall be decontaminated before laundering.

(3) Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program support needs.

(4) Prior to entry, all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.

(5) The universal biohazard sign shall be posted on entry doors to the controlled area and all internal doors. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter.

(6) Equipment and materials required for the management of accidents involving viable organisms shall be available in the controlled area.

(d) *BL-4—LS.* Guidelines for these operations are not established. If these